

U.S. Bioanalytical Testing Services Market Size, Share & Trends Analysis Report By Molecule (Small Molecule, Large Molecule), By Test, By Workflow, By End-use (Pharma & BioPharma Companies, CDMO, CRO), And Segment Forecasts, 2025 - 2030

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Abstracts

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Market Size & Trends

The U.S. bioanalytical testing services market size was estimated at USD 1.98 billion in 2024 and is expected t%li%grow at a CAGR of 9.33% from 2025 t%li%2030. The growth of the U.S. bioanalytical testing services industry is driven by several factors, such as the rising drug development and approval process, growing demand for biologics, biosimilars, and gene therapies, and rising outsourcing of testing services. In addition, Stringent FDA regulations are driving the need for precise bioanalytical testing. Furthermore, the expansion of bioanalytical testing facilities is another key aspect driving the market growth.

Several industry players and biopharmaceutical companies are investing significantly t%li%upgrade and expand their testing infrastructure t%li%meet the growing demand for advanced bioanalytical services. Moreover, a surge in the number of complex biologics, biosimilars, gene therapies, and personalized medicine development is further creating the need for sophisticated testing platforms t%li%perform complex bioanalyses, such as pharmacokinetics, biomarker discovery, and immunogenicity assessments.

Moreover, several service providers are developing state-of-the-art facilities integrated with high-resolution mass spectrometry (HRMS), NGS, and automation technologies



t%li%offer faster, more accurate, and cost-effective bioanalytical testing, further propelling market progression. For instance, in September 2024, Laboratory Corporation of America Holdings announced the completion expansion of its laboratory in Greenfield. The expansion aimed t%li%%li%support the development and validation of preclinical and clinical molecular bioanalytical testing services for advanced therapies, including cell and gene therapies for rare diseases, oncology, and other therapeutic areas. This expansion offered a competitive advantage t%li%the firm.

Increasing regulatory control and awareness regarding the importance of bioanalytical testing are key factors propelling the growth of the bioanalytical testing service market. The introduction of stringent guidelines on drug development, particularly in pharmacokinetics, pharmacodynamics, and bioequivalence testing by several regulatory agencies, such as the U.S. FDA and EMA, leads t%li%a rising preference for outsourcing. These guidelines highlight the need for precise and reliable bioanalytical methods t%li%enhance the safety and efficacy of new drugs & biosimilars. For instance, the U.S. FDA's Bioanalytical Method Validation Guidance provides clear standards for method development, validation, and sample analysis, which have driven pharmaceutical companies t%li%seek specialized expertise from contract service providers. Moreover, the market participants assist sponsors in complying with regulatory requirements by offering advanced analytical platforms and standardized protocols, driving market demand.

Likewise, technological advancements and growing R&D investments are key factors driving the U.S. bioanalytical testing service industry growth. The continuous developments of innovative technologies, such as High-Throughput Screening (HTS), Liquid Chromatography-Mass Spectrometry (LC-MS), and Next-generation Sequencing (NGS), have significantly enhanced the precision, speed, and sensitivity of bioanalytical testing. These innovations assist service providers in conducting more complex studies and gaining accurate data on drug efficacy, safety, and pharmacokinetics, among others. Moreover, integrating automation and Artificial Intelligence (AI) int%li%bioanalytical workflows streamlined processes, reduced human error, and improved throughput. Such factors are anticipated t%li%drive the market over the estimated period.

U.S. Bioanalytical Testing Services Market Report Segmentation

This report forecasts revenue growth at country level and provides an analysis of the latest industry trends in each of the sub-segments from 2018 t%li%2030. For this study, Grand View Research has segmented the U.S. bioanalytical testing services market



report based on molecule, test, workflow, and end-use:

Molecule Outlook (Revenue, USD Million, 2018 - 2030) Small Molecule Large Molecule LC-MS Studies Immunoassays Pharmacokinetics (PK) **ADA Assay** Other immunoassays Other Large Molecule Tests Test Outlook (Revenue, USD Million, 2018 - 2030) **ADME** In-vivo In-vitro Pharmacokinetics (PK) Pharmacodynamics (PD) Bioavailability Bioequivalence **Biomarker Testing** Cell-based Assay



Virology Testing Other Tests Workflow Outlook (Revenue, USD Million, 2018 - 2030) Sample Collection and Preparation Sample Collection, Handling and Storage **Protein Precipitation** Liquid-Liquid Extraction Solid Phase Extraction Others Method Development and Validation Sample Analysis Hyphenated Technique Chromatographic Technique Electrophoresis Ligand Binding Assay Mass Spectrometry Spectroscopic Techniques Nuclear Magnetic Resonance (NMR) Others



Genomic and Molecular Techniques
Polymerase Chain Reaction (PCR)
Next-Generation Sequencing (NGS)
Others
Other Processes
End Use Outlook (Revenue, USD Million, 2018 - 2030)
Pharma & BioPharma Companies
CDMO
CRO
Others



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